

# **Exhibit 6**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

MEDLINE INDUSTRIES, INC.,

Plaintiff,

v.

C. R. BARD, INC.,

Defendant.

Civil Action No. 1:14-cv-3618

Judge John Z. Lee

**JURY TRIAL DEMANDED**

**REBUTTAL EXPERT REPORT OF RICHARD HILLSTEAD, PH.D., REGARDING  
NON-INFRINGEMENT OF ASSERTED CLAIMS OF U.S. PATENT NOS. 8,448,786  
AND 8,678,190**

**(CONTAINS INFORMATION THAT HAS BEEN DESIGNATED AS CONFIDENTIAL  
AND HIGHLY CONFIDENTIAL)**

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(Jan. 11, 2019 Memorandum Opinion and Order (“Claim Construction Order”), ECF No. 348.)

52. For terms for which the Court did not provide a specific construction in its claim construction order, but which the parties have agreed on particular constructions, my opinions are based on the parties’ agreed upon constructions, as reflected in the parties’ Joint Claim Construction Chart and Status Report (“Joint Status Report”) filed on August 29, 2016, (ECF No. 283). These constructions are provided in the following table:

<b>Term</b>	<b>Undisputed Construction</b>
“barrier”	“Structure that separates one compartment from another and prevents or blocks movement there between”
“opening ... in a barrier”	“An aperture or gap defined by the barrier that allows passage of an object through the barrier”
“reveal”	“To make visible or to make (something that was hidden) able to be seen”

53. For any terms for which the Court did not provide a specific construction in its claim construction order, and for which the parties have not agreed on any particular constructions, my opinions are based on the ordinary and customary meaning from the perspective of a person of ordinary skill in the art at the time of invention when viewed in light of the respective patent’s specification and prosecution history.

### **VIII. THE ACCUSED PRODUCTS AND FEATURES**

54. I understand that Medline identifies only the SureStep tray as an infringing product.

55. I understand that Bard currently sells two versions of the accused SureStep tray. One is a smaller version in which the catheter is attached to a drainage bag. The other is a larger version in which the catheter is attached to a urine meter. My opinions concerning these currently sold versions of the SureStep tray are the same for each. In other words, any differences between the two versions of the SureStep trays currently sold today (the drainage bag tray and the urine meter tray) are immaterial to my opinions and conclusions expressed below. Particularly relevant to the asserted claims of the '190 patent, these trays do not include an opening in the wall separating the compartment storing the catheter and the compartment storing the syringes. As expressed below, it is my opinion that these trays cannot be used to infringe the asserted claims of the '190 patent.

56. I also understand that Bard previously sold two versions of the SureStep tray that are no longer sold. Again, one of those trays included a drainage bag attached to the catheter, and the other included a urine meter attached to the catheter. Any differences between the original meter tray and the original bag tray are immaterial to my opinions and conclusions expressed below.

57. I understand that Bard first began selling the SureStep tray in March 2014. (Feb. 12, 2016 Jeffrey Miller Dep. Tr. at 53:19–54:13.) I understand that when the SureStep trays were first sold, they included instructions for use to which a patient card was attached with perforations. Thus, the patient card could be separated from the instructions for use. However, I also understand that before the SureStep was first sold, Bard decided that it would manually separate the patient card from the instructions for use during the assembly and packaging process, such that the patient card was no



longer attached to the instructions for use when the SureStep trays were sold to customers. (Burn Dep. Ex. 24.) I also understand that in April 2014, shortly after releasing the SureStep tray in March 2014, Bard began to implement this change, such that only a small number of trays with the perforated cards still attached were sold for a short period of time. (BARD\_0218086.)

58. I also understand that beginning in November 2014 Bard began providing instructions for use that were never attached to the patient card in SureStep trays products. (BARD\_0218086; BARD\_0327015; BARD\_0327014.)

## **IX. GENERAL OBSERVATIONS REGARDING NON-INFRINGEMENT**

59. It is my opinion that Bard does not infringe any of the asserted claims of the '786 patent or the '190 patent, either directly or indirectly. In the next sections, I summarize my analysis, which shows that at least one limitation of each asserted claim of the '786 patent and '190 patent is not satisfied. Before analyzing each asserted claim, however, in this section I offer several general observations regarding the non-infringement of the asserted patents.

### **A. Medline Offers No Evidence or Expert Opinion Regarding Bard's Alleged Infringement of the '935 Patent**

60. I note that Medline's complaint alleges infringement of the '935 patent in addition to the '786 patent and the '190 patent. I understand, however, that Medline no longer asserts any claims of the '935 patent. (Medline Industries, Inc. Identification of Asserted Claims, dated Feb. 8, 2019 (identifying asserted claims from only the '786 patent and '190 patent).) I further understand that neither Ms. Weintraub nor Dr. Abraham offers any opinions concerning the '935 patent, and therefore they do

**a. placing one of the one or more layers of wrap or the additional layer of wrap beneath a patient**

85. After reviewing Ms. Weintraub's analysis of the step of "placing one of the one or more layers of wrap or the additional layer of wrap beneath a patient" of claim 1 of the '786 patent, it is my opinion that she does not provide any evidence that this step is or has been performed by any end-user. Ms. Weintraub states that it is her "opinion that this step is generally required by facility protocols in the United States and that, even in the absence of a controlling protocol, this step is always performed by clinicians using the SURESTEP product." (Weintraub Rpt. ¶ 311.) Ms. Weintraub fails, however, to include any of the "facility protocols" that she claims require clinicians to perform this step. Nor does Ms. Weintraub provide any evidentiary basis for her assertion that "this step is always performed by clinicians using the SURESTEP product." Ms. Weintraub has not provided evidence of this step being performed even one time by anyone, let alone every time a catheterization is performed. She merely expresses her opinion that "this step is always performed." In my view Ms. Weintraub's opinion that the step is always performed is insufficient to show that the step actually is or has been performed and clearly cannot be evidence that it is necessarily performed.

86. Based on my personal experience designing catheters and the trays they are packaged in, and witnessing firsthand the wide variety of environments where the products are used, it is my opinion that there are few procedural steps listed in the instructions for use that are actually "always" performed. To make such a statement reflects a lack of understanding of the many environments where this catheterization procedure is performed. Procedural trays such as the one discussed here, are carefully

designed to provide the practitioner with all of the components necessary to safely and effectively perform the procedure in a variety of settings. It should be understood that these catheters are inserted in male and female patients in settings ranging from people's homes to high-tech surgical suites. Additionally, those performing the procedures can be technicians, nurses, interns, physician assistants, or highly specialized physicians. The personnel involved can be one nurse operating alone in a nursing home or a team of operating room doctors and technicians in a sophisticated, "state-of-the-art" surgical suite.

87. Accordingly, those who actually design products and the procedural trays they are packaged in, strive to include the necessary accessories intended to facilitate insertion in any one of these settings. This does not mean that engineers expect or instruct every practitioner to use each and every item included in the tray in each and every procedure. Nor do engineers expect that each item, such as an underpad, will "always" be used in precisely the same fashion by each and every individual or in each and every procedural setting.

88. For instance, I have personally witnessed a wide range of practices in using a procedural tray when performing catheterizations. The tray may be positioned on a back table or side table or between the patient's legs as suggested in Bard's instructional video, and personnel carefully retrieve items from the tray and perform steps of the catheterization.

89. On other occasions, however, particularly in a sterile operating room environment, I have seen operators simply dump the entire tray of components on a large sterile drape between the patient's legs where they have easier access to pick up

the specific components they feel are necessary while wearing surgical gloves. In this scenario, it is not unusual to see many of the contents of the tray remain unused and quickly discarded in the trash. This is particularly true with procedures such as the insertion of a urinary catheter which is ancillary to the primary procedure. It is simply one of the steps that needs to be done so the surgeons can perform the brain surgery, heart transplant, etc. without the patient voiding their bladder during the operation.

90. It should also be understood that practitioners tend to execute procedures in the manner in which they were trained. If they learned to insert a Foley catheter without using an underpad, they are likely to default to their familiar procedural technique in the absence of any compelling reason to adopt a different technique.

91. Additionally, beyond the environment in which a procedural tray is used or the training a practitioner received, the wide anatomical differences of the patients who require insertion of a Foley catheter also can significantly affect how a catheterization procedure is performed and what equipment or supplies are necessary or even useful in completing the procedure. For example, even if it were a practitioner's preferred practice to place an underpad beneath a patient, when the patient weighs 400 pounds, placing the underpad beneath the patient may not be an option.

92. Ms. Weintraub also supports her opinion on the fact that the SureStep products include an underpad and the Directions for Use and an instructional video instruct the user to place the underpad under a patient. (Weintraub Rpt. ¶¶ 313–15.) From this she concludes the following: “Thus, this step is performed by clinicians using the SURESTEP product . . .” (Weintraub Rpt. ¶ 316.) Ms. Weintraub does not,

however, provide any evidence that clinicians actually follow this step of the Directions for Use or instructional video. And to the extent Ms. Weintraub relies on the instructional video itself, it cannot suffice as evidence of direct infringement because it does not show that each and every step of the claimed method is performed, let alone with a patient.

93. After reviewing Dr. Abraham's analysis of this claim element, it is my opinion that he too does not provide any evidence that this step is or has been performed by clinicians. In fact, Dr. Abraham merely relies on Ms. Weintraub's opinion, conceding that he is "not personally familiar with whether clinicians place the additional layer of wrap beneath a patient during a catheterization procedure." (Abraham Rpt. at 76.) Dr. Abraham states that he is "informed by Ms. Weintraub that (1) clinicians place the additional layer of wrap beneath the patient during a catheterization procedure." (Abraham Rpt. at 76.) Dr. Abraham concludes that "Based on this information from Ms. Weintraub, and based on Bard's lack of any noninfringement position regarding this step (Ex. 11), it is my view that this element also is met via use of the SureStep products." (Abraham Rpt. at 76.) Thus, it is clear that Dr. Abraham's only basis for concluding that this element is satisfied is Ms. Weintraub's unsupported opinion that it is satisfied every time a catheterization is performed. As explained above, Ms. Weintraub does not support her opinion with any evidence. To the extent Dr. Abraham relies on the instructional video itself, again it cannot suffice as evidence of direct infringement because it does not show that each and every step of the method is performed. As mentioned earlier in my report, Dr. Abraham also attempts to place the burden on Bard to prove that this particular element

is *not* satisfied. I understand that this attempt at shifting Medline's burden to affirmatively prove that each and every step of the claimed method is performed, to require Bard to prove the step is not satisfied, is contrary to established patent law.

94. Ms. Weintraub states in her report that "Bard designed the kit such that its ordinary use would necessarily result in the practice of these steps" of claim 1 of the '786 patent. (Weintraub Rpt. ¶ 332.) As explained above, based on my own experience, it is my opinion that every step of claim 1, including this step of "placing one of the one or more layers of wrap or the additional layer of wrap beneath a patient" is not necessarily performed. I also understand from Dr. Yun that this step of "placing one of the one or more layers of wrap or the additional layer of wrap beneath a patient" is not necessarily practiced and in fact is not always performed when catheterizing a patient. In particular, when patients undergoing surgery require a Foley catheter, clinicians in the operating room do not place one of the one or more layers of wrap or the additional layer of wrap beneath the patient. I understand from Dr. Yun that this step is unnecessary because the operating room is a sterile environment, and the patient undergoing surgery is already positioned within the sterile field on the operating table. Therefore, the one or more layers of wrap included in an accused SureStep tray is superfluous and is discarded.

95. I also understand that the evidence of record in this case shows that clinicians do not always perform this step of "placing one of the one or more layers of wrap or the additional layer of wrap beneath a patient." In particular, I understand that Medline deposed several clinicians in this case for the express purpose of gathering evidence of direct infringement by clinicians. Notably, neither Ms. Weintraub nor Dr.

Abraham cites these depositions as evidence of direct infringement in their respective reports. I have reviewed the deposition transcripts and videos, and multiple nurses testified that they do not perform this step when catheterizing patients. For example, Ms. Elizabeth Hultman of Iowa Methodist Hospital testified about the steps she performs when catheterizing a patient using the accused SureStep product. In enumerating the steps, she did not describe placing any layer of wrap beneath the patient. Instead, she testified that she places the wrap *on* the patient. (Apr. 8, 2016 Elizabeth Hultman Dep. Tr. at 50:13–52:5 (“Q. What drape are you referring to? A. The drape that goes in the perineal area, the genital area. Q. Is that another layer of wrap? A. Yes. . . . Q. Have you also revealed the underpad at this point? A. Yes. It would be the drape that I referred to earlier. Q. I want to make sure that I am doing everything in the right order before I have you move on. So once you’ve unwrapped the outer layer and accessed the catheter assembly and the gloves and the drape, what happens next? A. So then I would put on my sterile gloves. And after I’ve done that, I put my drape *on* the patient.”) (emphasis added).) Ms. Jekira Jackson also testified that she places the wrap on the patient’s thighs, not beneath the patient. (Apr. 21, 2016 Jekira Jackson Dep. Tr. at 46:18–20 (“Ok. So this drape is going *on* the patient’s thighs, extending to, I typically go on top of the scrotum.”) (emphasis added).) She later reiterated that she never places the wrap beneath a male patient. (*Id.* at 74:4-18 (“Q. Okay. So if you have a male patient you never place a wrap underneath the patient’s buttocks? A. Correct.”).)

96. Thus, based on my review of the reports of Ms. Weintraub and Dr. Abraham, my own experience, my discussion with Dr. Yun, and my review of the

*urethra. That's where I picked up that practice.*” (MI0022550 at 4); “Some lubricated the catheter by placing the catheter directly into the back end of the lubrication syringe . . .” (MI0022550 at 7.) I understand that Dr. Haywood’s observations did not involve the accused SureStep trays; nevertheless, his observations further demonstrate that clinicians have a variety of methods for using lubrication during the catheterization process, undermining Ms. Weintraub’s and Dr. Abraham’s unsupported assertions that clinicians always perform the step of “injecting lubricating jelly from the at least one syringe into the first compartment of the tray.”

137. Therefore, based on my review of the evidence of record indicating that clinicians do not perform the “injecting lubricating jelly from the at least one syringe into the first compartment of the tray” step when using the accused SureStep trays, my discussion with Dr. Yun that he and others inject lubricant directly into the urethra, Dr. Haywood’s observations that nurses lubricate the urethra directly or use the open syringe to lubricate the catheter, and Ms. Weintraub’s and Dr. Abraham’s failure to cite any evidence, it is my opinion that Medline has failed to prove with evidence that this step is performed by clinicians using the accused SureStep trays.

- b. passing at least a portion of the catheter assembly from a second compartment of the tray through an opening in a first barrier separating the first compartment from the second compartment, thereby passing the at least the portion of the catheter assembly through the lubricating jelly**

138. It is my opinion that Medline has not provided any evidence of anyone performing the step of “passing at least a portion of the catheter assembly from a second compartment of the tray through an opening in a first barrier separating the



first compartment from the second compartment, thereby passing the at least the portion of the catheter assembly through the lubricating jelly” of the claimed method when using the accused SureStep trays. I understand that the accused SureStep trays that currently are sold do not include “an opening in a first barrier separating the first compartment from the second compartment.” Accordingly, it is my opinion that it is not possible for this step to be performed by clinicians using the accused SureStep trays as they are sold today.

139. For the versions of the accused SureStep trays that were sold when it was initially launched, which Ms. Weintraub identifies in her report as Tray A design and Tray B design and Dr. Abraham identifies in his report as Tray Nos. 1 and 2, I have not seen any evidence identified by Medline showing specific instances where clinicians actually performed this step using the accused SureStep trays. In particular, neither Ms. Weintraub nor Dr. Abraham cite any evidence of clinicians performing this step. Ms. Weintraub merely states that it is her “opinion that this is frequently done by clinicians when using those SURESTEP products that contain an opening between the catheter assembly compartment and the syringe compartment.” (Weintraub Rpt. ¶ 390.) Not only does Ms. Weintraub not cite any evidence of a clinician actually performing the step, she concedes that in her opinion it is neither always performed nor necessarily performed when using the SureStep trays. (*Id.*) Ms. Weintraub goes on to speculate “Based on [her] own use of these products and witnessing others use them . . . that this step is practiced roughly 50% of the time by clinicians using the SURESTEP tray with this feature.” (*Id.* ¶ 398.) Ms. Weintraub does not cite any evidence in her report supporting her bold assertion that this step is performed at all, let alone that it is

performed 50% of the time. It appears that the 50% figure is no more than pure speculation by Ms. Weintraub.

140. Dr. Abraham similarly does not cite any evidence that this step is performed by clinicians when using the accused SureStep trays. Instead, he merely relies on the opinion of Ms. Weintraub: “Ms. Weintraub has advised me that clinicians did use these openings to pass the catheter therethrough for lubrication after the lubrication jelly has been deposited into the syringe well. Based on this information from Ms. Weintraub it is my opinion that this step also is met in the use of the SureStep kits . . . .” (Abraham Rpt. at 88.) Later, however, Dr. Abraham retreats slightly, stating that “Ms. Weintraub advises that, for Trays 1 and 2, the catheter is *sometimes* passed through the opening after the lubrication jelly has been injected.” (*Id.* at 89 (emphasis added).) Because Dr. Abraham merely relies on Ms. Weintraub’s opinion, he similarly fails to provide any evidence of clinicians actually performing this step while using the accused SureStep trays.

141. It is my opinion that this step is not necessarily performed when using the accused SureStep trays to catheterize a patient. In particular, I understand from Dr. Yun that lubricant may be used in a variety of ways and not necessarily by “passing at least a portion of the catheter assembly from a second compartment of the tray through an opening in a first barrier separating the first compartment from the second compartment.” For example, I understand that lubricant could be applied directly on the catheter, which is preferable to some clinicians because it does not require the catheter to be moved within the tray. (Expert Report of Dr. Edward Yun Related to Invalidity, dated June 13, 2019 (“Yun Rpt.”), ¶ 39.) Additionally, I

### **XIII. CONCLUSION**

208. This report is based on my present review and analysis of materials and information currently available to me. My investigation and analysis may continue, which may include reviewing documents and other information that may yet be made available to me. Thus, I expressly reserve the right to continue my study in connection with this case and to expand or modify my opinions and conclusions as my study continues.

209. I declare under penalty of perjury under the law of the United States of America that the foregoing is true and correct.

Executed on: July 25, 2019

  
Richard Hillstead